



COT - 2001

BIOMUNE INC.
8906 Rosehill Road
Lenexa, Kansas 66215

Phone: 913-894-0230
FAX: 913-894-0236

October 3, 2001

Office of Special Nutritionals (HFS-450)
Center for Food Safety and Applied Nutrition
Food and Drug Administration
200 C Street, SW
Washington, DC 20204

78644

RE: Notification of Additional Dietary Supplement Marketing Claims

Dear Sir/Madam:

Pursuant to 21 CFR §101.93 this is to notify you that Biomune Inc. will be marketing a dietary supplement containing the structure/function claims as indicated below.

1. Name and Address of Manufacturer and Distributor:

Manufacturer:

Soft Gel Technologies, Inc.
95 Oser Avenue, Suite C
Hauppauge, New York 11788
Phone (631) 231-4900

Distributor:

BIOMUNE INC.
8906 Rosehill Road
Lenexa, Kansas 66215
Phone (913) 894-0230

2. Text of Statement:

The following statement will be made in marketing the product:

"This product:

a) may help maintain a healthy heart.

3. Description of Dietary Ingredient or Supplement:

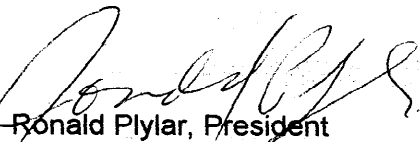
The product is a capsule formula containing the ingredients described in the attached nutritional information table (See attached label).

4. Name of Dietary Supplement:

"CoQ10 Dietary Supplement"

5. Certification of Accuracy:

I, Ron Plylar, President of Biomune, Inc., do hereby certify that the information contained in this notice is complete and accurate and that Biomune, Inc. has substantiation that the statement to be made is truthful and not misleading.


Ronald Plylar, President
Biomune Inc.

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Coenzyme Q10 is essential to the production of energy by the cells in your body. It is a key antioxidant nutrient and may help maintain a healthy heart.*

Suggested Use:

As a dietary supplement, adults take one or more capsules daily with a full glass of water. Warning: Pregnant or nursing women should contact their physician before using this product.

Store in a cool, dry place, tightly closed.

* The Food and Drug Administration have not evaluated these statements. This product is not intended to diagnose, treat, cure or prevent any disease.

CoQ10® is a registered trademark of Soft Gel Technologies, Inc. Bioene® is a registered trademark of Cognis Corp.

Serial No.
Exp. Date

BIOMUNE INC.
LENEXA, KS 66215 USA
Phone (913) 894-0230

BIOMUNE™

CoQsol®

MAXIMUNE™
CoQ - 10

Dietary Supplement

30 mg

Highly Bio-available

30 Softgels

EACH SOFTGEL CAPSULE CONTAINS			% Daily Value
Coenzyme Q10 (as CoQsol®)	30 mg		—
Rice Bran Oil	220 mg		—
Vitamin E (with mixed Tocopherols)	30 I.U.		100%
Vitamin A (from Carotene D, Salina)	1200 I.U.		24%
Beta Carotene (Betaene®)	700 mcg		—
Yellow Borage	12 mg		—

**Daily Value Not Established
Other Ingredients: Gelatin, Glycerin, Water, Annatto Extract, Titanium Dioxide. Contains No Added: Sugar, salt, starch, dairy, yeast, wheat, corn, preservatives, artificial colors or flavors.

SUPPLEMENT NUTRITION FACTS		
Serving Size: 1 Softgel	Amount	Calories
Total Fat	263.32 mg	2.37
Saturated Fat	44.90 mg	0.40
Unsaturated Fat	218.42 mg	1.97
Monounsaturated Fat	106.68 mg	0.96
Polysaturated Fat	111.74 mg	1.01
Total Carbohydrate	44.35 mg	0.18
Protein	92.30 mg	0.37
Cholesterol	0 mg	—